GENERAL ETHICS

# Rights, responsibilities and NICE: a rejoinder to Harris

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Harris' reply to our defence of the National Institute for Clinical Excellence's (NICE) current cost-effectiveness procedures contains two further errors. First, he wrongly draws a conclusion from the fact that NICE does not and cannot evaluate all possible uses of healthcare resources at any one time and generally cannot know which National Health Service (NHS) activities would be displaced or which groups of patients would have to forgo health benefits: the inference is that no estimate is or can be made by NICE of the benefits to be forgone. This is a non-sequitur. Second, he asserts that it is a flaw at the heart of the use of quality-adjusted life years (QALYs) as an outcome measure that comparisons between people need to be made. Such comparisons do indeed have to be made, but this is not a consequence of the choice of any particular outcome measure, be it the QALY or anything else.

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We are heartened that Harris accepts our characterisation of the allocation problem in healthcare, whether the good of health is defined as health gain (measured by quality-adjusted life years (QALYs) or other metric) or by some other, as a yet-to-be clearly defined, rights-based measure.[1] The disagreement now only turns on two issues: one is what we believe to be an epistemological misunderstanding; the other is a more substantive and widely debated issue about the measure of the good of healthcare.

## ABSURDLY ABUSIVE

Firstly, we have no comment to make on the balance of corporate versus personal abuse in these recent exchanges. Our own view is that those responsible for corporate policy are also morally accountable for and personally answerable to criticisms and moral condemnation of such policies. Others may differ. We are content for readers of the exchange to come to their own view of the absurdity of our interpretation of the previous editorials and the distinctions offered—with or without the assistance of the Oxford English Dictionary. We also leave readers to judge whether the National Institute for Clinical Excellence's (NICE's) attempts to follow their consciences and the instructions of the Secretary of State, by having regard to citizens' values, are fairly described as "populist".

## COST-EFFECTIVENESS

Of more substance is the apparent confusion about how decisions of cost-effectiveness can be made in a healthcare system like the National Health Service (NHS). Harris suggests that our paper implies that, "no estimate is or can be made by NICE of the benefits to be forgone", and therefore, "NICE, in the expert opinion of Claxton and Culyer, cannot and is not making its decisions on the basis of cost-effectiveness."[1]

To support this, Harris quotes and is referring to the following passage by us: "NICE does not and cannot evaluate all possible uses of healthcare resources at any one time and generally cannot know which NHS activities will be displaced or which groups of patients will have to forgo health benefits". Harris is certainly correct about this. But what may be inferred from this? Again, it is not clear what he is arguing about.[2] Our question was somewhat rhetorical. We continued, "The two obvious possibilities are:

- there will be no real costs because other activities will not be displaced and health benefits will not be forgone
- because the individuals bearing the cost are unidentified and unknown, their health losses or lost opportunities to benefit are less important or of no consequence compared to the groups of patients under consideration who may benefit from treatment."[2]

Our point was that neither NICE nor any other decision-making entity, including a practising physician at the bedside, can know precisely which NHS activities would be displaced by their guidance or by prescribing decisions, or exactly who will forgo which specific health benefits. However, we do know that there will be health forgone to real, albeit unidentified, patients, and we maintain the value judgement that the consequences for those unidentified individuals ought to be valued in the same way as the consequences for others who gain from the technology under consideration (or who are in the bed) and who are currently identified and known.

Harris seems to have assumed the obvious fact that no institution or individual can know at any one point in time precisely who will forgo a health benefit to imply that we have no way of assessing whether "the health benefits that it is estimated could be gained from the technology are less than those estimated to be forgone by other patients".[1 2]

Such an estimate requires some knowledge of the health gained by some of the least productive (in terms of health outcome) of the activities currently undertaken by the NHS. Therefore, to say we know nothing and have no estimate of the health forgone is to say that we have no knowledge of the

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**Abbreviations:** NHS, National Health Service; NICE, National Institute for Clinical Excellence; QALYs, quality-adjusted life years productivity of any NHS activity. This is absurd. NICE itself has generated substantial evidence of the cost-effectiveness of interventions currently undertaken (and not undertaken) in the NHS. There is also a much wider body of evidence that can be easily accessed (eg, the NHS Economic Evaluation Database). In addition, NICE engages in a broad consultation process with all stakeholders, including the nation's foremost clinical generalists, experts in the management of the diseases and treatments under examination, and the general public, to identify technologies for both investment and disinvestment. The proposals obtained through the consultation process are reviewed by two expert committees: the Advisory Committee on Topic Selection, and the Joint Planning Group, who use their broad knowledge of the efficiency of a wide range of NHS interventions in considering which therapies to put forward for review.

This approach usually embodies the seemingly reasonable assumption that, where NICE has not identified a concurrent disinvestment, local decision makers in the NHS will, in general, curtail activities that provide less rather than more health gain. If in general they do not and, for example, displace activities at random, then the forgone health will be even higher than when only the least productive activities are carefully identified and displaced. In these circumstances the estimate of the health forgone should be higher (reflecting the average rather than marginal productivity of healthcare), making it much less likely that interventions such as the drugs for Alzheimer's disease or multiple cycles of intravenous fluid can be regarded as cost-effective.[3]

There is a substantial literature addressing how these decisions can be made in these common circumstances, including the NICE methods guidance itself.[4 5] Our mistake was to take this literature as read, which hardly amounts to a ''fatal flaw''.

There is an important debate and a body of literature about how decision makers within a healthcare system can improve decision making at national and local levels when they are uncertain about the gains from technologies and the forgone health benefit elsewhere.[5] Harris may have intended to point out that precision greater than that provided by current estimates would be valuable. He may also believe that the central estimate of what will be displaced may be incorrect. If so, we agree on both counts: generating information to inform the Institute (or other decision-making entities) whether the guidance issued might displace more health than it generates (or vice versa) is obviously very important. At present, given the funding for the NHS and the difficulties faced by local commissioners and clinical governance managers, the estimates of forgone health may be too low. As far as we are aware, no informed commentator is suggesting it is too high. However, if this is his concern, then, by all accounts, the provisional guidance to withhold treatment for Alzheimer's disease (a decision to which Harris objected, and the origin of these exchanges) would have been more rather than less secure.

We find it hard to believe that Harris really holds that it is impossible to estimate what may be forgone in the healthcare system on the grounds that one cannot be precise about identities or quantities. We therefore conclude that his objection is based on a misunderstanding and are content to let readers judge whether there is a ''fatal flaw'' in our argument or—much more importantly—in the methods used by NICE to make its inevitably difficult decisions about healthcare priorities in an explicit and transparent way.

## THE GOOD OF HEALTHCARE

Harris' imaginary example of the twin sisters raises again two matters that are inherent in nearly all resource-allocation decisions and have been the subject of a large and venerable literature.[6] The first is that healthcare resources available are insufficient to permit all who may have Mars Jones' ''unfinished business'' to be able to conclude it. This may mean that neither of the twins may receive care from which it is conceivable that they may benefit or that both may, or that only one may. Harris refuses to take responsibility for the unavoidable choice he has posed, ''it is unethical to choose between them…there is no rational basis for so doing''.[1] Abdication of responsibility for this decision does not mean it will not be made; instead both, neither or one will ultimately receive care on the basis of some opaque and possibly arbitrary process, and the cost in terms of lost lives (long or short) will be ignored.

The other matter is the question of which, if only one can receive care, ought to have it. This is a question of interpersonal comparisons that the QALY methodology has starkly raised. It is not a ''flaw at the heart of the QALYs''[1] that comparisons between people need to be made. The question of how best to make interpersonal comparisons is not one that is in any way specific to QALYs; it arises in virtually all comparisons of future health, whether measured by QALYs or in some other way, including the sorts of measure preferred by Harris that are invariant with respect to life expectation. We count it as a virtue of the QALY method that it highlights the question and has enabled its extensive discussion in the QALY-related literature, to which we referred in our previous comment—that has many more dimensions to it than that of the potential ''ageism'' to which Harris attaches such signal importance. God has not granted the hours, but he may be said to have granted society the right to make choices and the duty of taking responsibility for them. Although exercising these choices implicitly and opaquely might provide some comfort to decision makers and commentators, it will serve neither accountability nor democracy—nor, we conjecture, social justice.

It seems to us that the best way of handling such questions, once they have been identified and whatever evidence concerning them gathered and assessed, is by a deliberative process, despite the risk of being charged with ''populism''. This is what NICE has done in response to the requirements of the secretary of state. On such matters, it has consulted its Citizens' Council. Indeed, NICE has recently consulted the Citizens' Council on precisely the issues raised by Harris in his two examples.[7]

The *Citizens' council report on the rule of rescue* makes for interesting reading.[7] They found precise and explicit definitions almost impossible, and the trade-offs between immediate risk and health gain to others even more difficult. All members rejected a clearly defined rule of rescue (an imperative to save life) and focused instead on the circumstances when exceptions to decisions based on health gain could be made. A minority of the Council rejected any exceptions based on rescue; a majority suggested that concerns for rescue should not be completely rejected, but should be applied only in exceptional circumstances. These circumstances include a ''good probability of increased life expectancy'' and ''a significant improvement in quality of life''. However, the council was unable to define ''good probability'', ''increased life expectancy'' or ''significant improvement in quality''. All agreed that any exceptions based on rescue should consider the opportunity costs (forgone health to others), but were unable to specify the trade-off that should be made. One reason why the Citizens' Council found it so difficult to provide precise and explicit answers to these questions is that they took their duty to explore fully the implications of holding particular views seriously.

## RIGHTS AND RESPONSIBILITIES

All societies ought to have the right to comment on the processes, deliberations and recommendations made by NICE on behalf of the NHS, but those who exercise that right, and whose wish to engage and inform the decision makers, commonly take responsibility for fully exploring the implications—for the whole of society—of the positions they hold. However, commentators who choose to abdicate this responsibility face no such discipline. Their reward is the freedom of the nihilist, who has no duty to offer alternative solutions, let alone any solutions that are precise, explicit or fully explored. The defence of academic freedom, sometimes combined with pedantry, is always available to those who choose such a course, and it should be recognised for what it is.

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Competing interests: KC is a member of the National Institute for Clinical Excellence's Appraisals Committee, and was a member of the working party that recommended NICE's current methodology for the conduct of economic appraisals; AJC was a member of the NICE Board that commissioned and accepted this work, and, although no longer on the Board, remains a member of NICE's Research and Development Committee.

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